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09/595,947	06/16/2000	Christine Icard-Liepkalns		2918

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/595,947	ICARD-LIEPKALNS ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *11-18,31-38 and 47-66* is/are withdrawn from consideration.

5)☒ Claim(s) *27-30 and 43-46* is/are ~~allowed~~ allowable over art of record

6)☒ Claim(s) *1-10,19-26 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/331,356.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/20/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. In the response to restriction requirement filed January 9, 2003, claim 1 has been amended to correct an error in "SEQ ID NO:" and "SEQ ID NO:10" has been changed to "SEQ ID NO:1", however, claims 2-10 remain uncorrected. To advance prosecution, "SEQ ID NO:1" is treated as the claimed nucleotide sequence for claims 2-10. Applicant's election with traverse of Group I, claims 1-10, 19-30 and 39-46, drawn to a nucleic acid comprising a polynucleotide sequence of SEQ ID NO:1 or a complementary polynucleotide sequence, a recombinant vector or a host cell comprising the nucleic acid, and a pharmaceutical composition comprising the nucleic acid, is acknowledged. The traversal is on the ground(s) that the groups of the claims designated by the Examiner fail to define compositions and methods for using the compositions with properties so distinct to warrant separate examination and search, e.g., Groups II and III are classified in the same class 536 as Group I, and examination of these groups (Groups I, II, and III) or all the claims of the present application can be made without serious burden (pages 7-8 of the response). Applicants request rejoinder of all the groups or at least Groups I, II and III (page 8 of the response). The response has been considered, the argument is found not persuasive regarding rejoining all the groups because Groups IV, VII and XI, directed to a polypeptide and a method of using the polypeptide, and Group V directed to an antibody are distinct chemical entities from the polynucleotide, vector or host cell of Group I; and a kit for amplifying the nucleic acid (Group II), a kit for detecting the nucleic acid (Group III), and an implant comprising the recombinant host cell (Group IX) are directed to entities that have different modes of operation and different utilities from

the product of Group I, thus these groups are distinct from Group I. As to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved, coexamination of each of the additional groups would require additional search of different art area. The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not coextensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other group. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist.

Regarding rejoining the process claims of Group I, please see the following paragraphs:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Sequence Listing

2. The Sequence Listing filed December 8, 2003 is acknowledged, CRF has been entered.

Informalities

The disclosure is objected to because of the following informalities:

3. The specification recites amino acid and nucleotide sequences (e.g., Figs. 1-4), however, the sequence identifier "SEQ ID NO:" is not indicated in the Description of the Drawings (pages 10-11). Applicant must comply with the requirements of sequence rules (37 CFR 1.821-1.825) to include all the sequences in the sequence listing and to identify each sequence with a "SEQ ID NO:". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2-5, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2-5, 7 and 8 are directed to a nucleic acid comprising at least 8 consecutive nucleotides of SEQ ID NO:1, or a complementary polynucleotide sequence thereof (claim 2); a nucleic acid comprising at least 80%, or 85%, 90%, 95% or 98% nucleotide identity with nucleic acid comprising SEQ ID NO:1, or a complementary polynucleotide sequence thereof (claims 3, 4); a nucleic acid that hybridizes under high stringency conditions with a nucleic acid comprising SEQ ID NO:1, or a complementary polynucleotide sequence thereof (claim 5); and a nucleotide probe or primer specific for an ngn3 nucleic acid, wherein the nucleotide probe or primer comprising at least 15 consecutive nucleotides of SEQ ID NO:1, or a complementary polynucleotide sequence

thereof (claims 7 and 8). The specification indicates that the invention relates to a nucleic acid having at least 80%, 85%, 90%, 95% or 98% sequence identity with a nucleic acid comprising SEQ ID NO:1; to a nucleic acid comprising at least 8 consecutive nucleotides of SEQ ID NO:1; to nucleic acid hybridizing under high stringency conditions with a nucleic acid comprising SEQ ID NO:1; to a nucleotide probe or primer comprise a fragment or a full length of a polynucleotide sequence of SEQ ID NO:1; and a nucleic acid encoding variants or analogs of a polypeptide, that have the same functional activity as the polypeptide (page 66, lines 12-20; page 29, line 21-page 31, line 4; page 66, lines 5-25). However, the specification does not specify which portion of the nucleic acid is identical to SEQ ID NO:1, which fragment of SEQ ID NO:1 is used as a probe or primer nucleotide, or which fragment of SEQ ID NO:1 encodes a biologically active polypeptide. There is no disclosure indicating various fragments of SEQ ID NO:1 are used as probe or primers, and the specification has not identified a nucleic acid variant or fragment which encodes a biologically active polypeptide. Without guidance for structure to function/activity, one skilled in the art would not know which fragment or variant of SEQ ID NO:1 encodes a functional polypeptide, which fragment of SEQ ID NO:1 is used as a probe or primer for a ngn3 nucleic acid, and how to identify a functional polypeptide. The lack of a structure to function/activity relationship and the lack of representative species for the polynucleotide having at least 80% sequence identity to SEQ ID NO:1, or the fragment of SEQ ID NO:1 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10, 19-26 and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1-10, 19-26 and 39-42 are indefinite because of the term "of a complementary polynucleotide sequence" or "a complementary polynucleotide sequence". The term "of a complementary polynucleotide sequence" or "a complementary polynucleotide sequence" renders the claim indefinite, it is not clear to what sequence the polynucleotide is complementary, e.g., is it to SEQ ID NO:1 or to other nucleotide sequences or to only a part? Claims 4, 8, 10, 19-26 and 39-42 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

7. Claims 2-10, 21-22, 24, 26, 40 and 42 are indefinite because the claim cites "SEQ ID NO:10" as a polynucleotide sequence, while "SEQ ID NO:10" is an amino acid sequence in the sequence listing, it is not clear how "SEQ ID NO:10" can be a polynucleotide sequence. Claims 8, 10, 21-22, 24, 26, 40 and 42 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1-6, 19, 21 and 23-26 are rejected under 35 U.S.C. 102(b) as anticipated by Bejanin *et al.* (J. Neurochemistry 58, 1580-1583, 1992).

Bejanin *et al.* teach a 1902-bp HindIII DNA fragment, which contains a promoter sequence of rat choline acetyltransferase (CHAT), selected by Southern hybridization using oligonucleotide 2 as the probe was subcloned at the HindIII site of the M13mp19 vector and the sequence was determined (Fig. 1; claims 1-6), and the 1902-bp HindIII DNA fragment was subcloned into the pUC18CAT vector (claims 19, 21, 23) and tranfected in embryonic septal cells (page 1581, right column; claims 24-26). Since the claim does not specifically identify the complementary polynucleotide sequence (see

paragraph 6 above), thus any polynucleotide that hybridizes with a nucleotide sequence meets the criteria of the claim.

9. Claims 1-7, 9, 19, 21 and 23-26 are rejected under 35 U.S.C. 102(e) as anticipated by Anderson *et al.* (U. S. Patent 6,566,496, priority date September 27, 1996).

Anderson *et al.* teach a nucleotide sequence of mouse neurogenin 3 (SEQ ID NO:19 in the patent), where nucleotides 463-554 of SEQ ID NO:19 have 100% sequence identity to nucleotides 762-853 of SEQ ID NO:1 (see attached sequence match; column 3, lines 44-45, Figs 9A and 9B; claim 2). The reference also teaches recombinant nucleic acids encoding neurogenins such as neurogenin 2 (Figs. 7A, 7B, 7C) and neurogenin 3 (Figs. 9A and 9B; claims 1-6), expression vectors (claims 19, 21, 23) comprising transcriptional and translational regulatory DNA operably linked to DNA encoding a neurogenin protein and host cells containing the expression vectors (column 2, lines 56-62; columns 20-23; claims 24-26); and PCR fragments encoding the helix 1-loop domain of ngn3 used as hybridization probes to isolate clones containing additional coding sequences from a mouse genomic library (column 20, lines 32-column 21, line 17; claims 7 and 9). Since the claim does not specifically identify the complementary polynucleotide sequence (see paragraph 6 shown above), thus any polynucleotide that hybridizes with a nucleotide sequence meets the criteria of the claim.

Conclusion

9. Claims 1-10, 19-26 and 39-42 are rejected. It appears claims 27-30 and 43-46 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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February 16, 2004